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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,375	02/18/2004	**Stefan M. Pulst**	066783-0145	3578

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EXAMINER
MONTANARI, DAVID A

ART UNIT	PAPER NUMBER
1632	

NOTIFICATION DATE	DELIVERY MODE
04/02/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

SIP_Docket@mwe.com

Office Action Summary	Application No.	Applicant(s)	
	10/782,375	PULST ET AL.	
	Examiner	Art Unit	
	David Montanari	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1, drawn to an isolated polypeptide, classified in class 530, subclass 350.

II. Claims 2-5, drawn to an antibody and a method of using said antibody, classified in class 530, subclass 387.1.

III. Claims 6-14, drawn to an isolated nucleic acid, a vector comprising said nucleic acid and a host cell comprising said vector, classified in class 536, subclass 23.1.

IV. Claim 8 and 14, drawn to an anti-sense strand comprising between 15 and 300 contiguous nucleotides of SEQ ID NO: 3 and a kit comprising said anti-sense strand, classified in class 536, subclass 24.5.

V. Claim 16, drawn to a method of identifying a candidate drug for treating Parkinson's disease comprising the use of a parkin binding polypeptide, wherein said parking polypeptide is synaptotagmin I, wherein said method uses a cell-free assay, classified in class 435, subclass 7.1.

VI. Claim 16, drawn to a method of identifying a candidate drug for treating Parkinson's disease comprising the use of a parkin binding polypeptide, wherein said parking polypeptide is synaptotagmin XI, wherein said method uses a cell-free assay, classified in class 435, subclass 7.1.

VII. Claim 16, drawn to a method of identifying a candidate drug for treating Parkinson's disease comprising the use of a parkin binding polypeptide, wherein

said parking polypeptide is a synapsin-like protein, wherein said method uses a cell-free assay, classified in class 435, subclass 7.1.

VIII. Claim 19, drawn to a method of identifying a candidate drug for treating Parkinson's disease comprising the use of a cell expressing a parkin binding polypeptide, wherein said parking polypeptide is synaptotagmin I, classified in class 435, subclass 7.1.

IX. Claim 19, drawn to a method of identifying a candidate drug for treating Parkinson's disease comprising the use of a cell expressing a parkin binding polypeptide, wherein said parking polypeptide is synaptotagmin XI, classified in class 435, subclass 7.1.

X. Claim 19, drawn to a method of identifying a candidate drug for treating Parkinson's disease comprising the use of a cell expressing a parkin binding polypeptide, wherein said parking polypeptide is synapsin-like protein, classified in class 435, subclass 7.1.

XI. Claim 21, drawn to a method of treating Parkinson's disease comprising the administration of a molecule that decreases expression or activity of a parkin binding polypeptide, wherein said parking polypeptide is synaptotagmin I, classified in class 514, subclass 44.

XII. Claim 21, drawn to a method of treating Parkinson's disease comprising the administration of a molecule that decreases expression or activity of a parkin binding polypeptide, wherein said parking polypeptide is synaptotagmin XI, classified in class 514, subclass 44.

XIII. Claim 21, drawn to a method of treating Parkinson's disease comprising the administration of a molecule that decreases expression or activity of a parkin binding polypeptide, wherein said parking polypeptide is a synapsin-like protein, classified in class 514, subclass 44.

XIV. Claim 23, drawn to a method of generating an animal model of Parkinson's disease, wherein the animal expresses an increased level of synaptotagmin I, classified in class 800, subclass 21.

XV. Claim 23, drawn to a method of generating an animal model of Parkinson's disease, wherein the animal expresses an increased level of synaptotagmin XI, classified in class 800, subclass 21.

XVI. Claim 23, drawn to a method of generating an animal model of Parkinson's disease, wherein the animal expresses an increased level of a synapsin-like protein, classified in class 800, subclass 21.

Inventions I-IV are directed to related products. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct since each invention has a materially different and distinct structure. Each of the claimed inventions has separate uses which would require a separate and burdensome search of the art. Furthermore, the inventions as

claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions V-VII are directed to related processes. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are each distinct since each method of identifying uses a distinct parkin binding polypeptide. The parking binding polypeptides are each distinct structurally and thus would require a separate search in the art. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions VIII-X are directed to related processes. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct since each method of identifying uses a distinct parkin binding polypeptide. The parking binding polypeptides are each distinct structurally and thus would require a separate search in the art. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions V-VII and VIII-X are directed to related processes. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a

materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct since the methods of inventions VIII-X are limited to contacting in a cell and the methods of inventions V-VII encompass cell-free assays. Cell-free assays and cell-based assays are materially different in design and mode of operation and thus would require separate searches in the art. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions XI-XIII are directed to related processes. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are each distinct since each method of treating Parkinson's disease uses a distinct molecule that decreases expression or activity of a parkin binding polypeptide. The parking binding polypeptides are each distinct structurally and thus would require a separate search in the art for the molecules that decrease expression or activity. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions XIV-XVI are directed to related processes. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants.

See MPEP § 806.05(j). In the instant case, the inventions as claimed are each distinct since each method of generating an animal model of Parkinson's disease uses a distinct parkin binding polypeptide. The parking binding polypeptides are each distinct structurally and thus would require a separate search in the art. Further each transgenic animal generated by methods of inventions XIV-XVI would have unrelated phenotypes or characteristics that would be distinct among each transgenic animal, further necessitating a separate search in the art. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions I and V-XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the isolated polypeptide (a parking binding polypeptide) of invention I, while being used in the methods of inventions V-XVI, the methods of inventions V-XVI can use separate and distinct parkin binding polypeptides which are structurally dissimilar from the polypeptide of SEQ ID NO:2.

Inventions III and VIII-X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the host cell comprising a vector encoding a polypeptide, while

being used in the methods of inventions VIII-X, the methods of inventions VIII-X can use a separate and distinct host cell expressing a distinct parkin binding polypeptide.

Claim 16 link(s) inventions V-VII. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 16. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Claim 19 link(s) inventions VIII-X. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 19. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Claim 21 link(s) inventions XI-XIII. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 21. Upon the indication

of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Claim 23 link(s) inventions XIV-XVI. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 23. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so**

may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is (571)272-3108. The examiner can normally be reached on M-Tr 8-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 1-571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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